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HAMRE, SCHUMANN, MUELLER & LARSON P.C.
P.O. BOX 2902
MINNEAPOLIS, MN 55402-0902

EXAMINER	
DIETERLE, JENNIFER M	

ART UNIT	PAPER NUMBER
1795	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/578,988	Applicant(s) FUJIWARA ET AL.	
	Examiner Jennifer Dieterle	Art Unit 1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *3/1/2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *5/11/06* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/22/09, 3/8/10*.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 1-31 are pending and being examined.

Response to Amendment/Arguments

1. Applicant's arguments filed 3/1/2010 have been fully considered but they are not persuasive. Applicant remarks that Kuhn in view of Hodges does not suggest the present invention. Specifically, applicant remarks that Hodges merely teaches that various chemical entities (i.e. mediators) can be provided as desired at various locations in the reaction cell of a sensor; however, Hodges does not provide any teaching about a particular location for the mediator and does not teach or hint that a mediator is associated with a counter electrode and not with a working electrode.

These remarks are not persuasive and it is noted that Hodges is utilized as a teaching reference to show that the placement of mediator is a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed location was significant. Hodges is utilized to show that it is known in the art that a mediator can be positioned based on the user preference at numerous areas within a reaction chamber such as on an electrode, a wall, a support or be self supportive and the device will still function in a predictable manner (i.e. promote a redox reaction for the detection of analyte). Hodges shows that the shifting of the position of the redox reagent with regard to the electrodes

is a matter of user preference in that the redox reaction will still proceed and a current will still be measured in order to determine an analyte of interest. See *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966); MPEP 2144.04 IV B.

Applicant also remarks that the presence of the mediator at both the working and counter electrode of Kuhn is a critical aspect; however, based on Hodges, it is evident that in a sensing device, regardless of the positioning of the mediator within the reaction chamber, a redox reaction will occur. Therefore, since Kuhn contains electrodes and sensing chemistry, the device will function and a redox reaction will transpire regardless of the placement of the mediator in the device of Kuhn and the court has held that when prior art reads on an arrangement of a part wherein the arrangement will not modify the operation of the device, the mere rearrangement of parts is unpatentable. See *In re Japikse*, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950); MPEP 2144.04 VI C.

Therefore, applicant's remarks are not persuasive and it would have been obvious to one skilled in the art to place a redox reagent at a desired location within the reaction chamber as shown in Hodges, for example on the counter electrode and not on the working electrode in Kuhn et al. since the sensor will operate with predictable result of a redox reaction transpiring and the detection of the electrochemical result.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 1, 13, 12, 15, 26, 27-28 and 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuhn et al. (US 5,385,846) in view of Hodges et al. (US 6,632,349 B1).

Regarding claims 1 and 13, Kuhn et al. teach a method of measuring hematocrit in a blood sample utilizing electrochemical techniques (abstract). The sample of blood

is infused with reagent and when a potential is applied ferryocyanide at the working electrode is oxidized to ferricyanide and the ferricyanide at the more negatively charged electrode is reduced to ferrocyanide and a current results and is measured to determine the hematocrit level (col. 4, lines 1-29). Kuhn et al. teach a two electrode sensor with a working electrode 4 and a counter electrode 5 (see figure 2; col. 2, lines 63-64). Kuhn et al. also teach a mesh layer 9 hat covers both electrodes and is infused with reagent (col. 3, lines 21-30).

Kuhn et al. does not teach that the reagent is not on the working electrode.

Hodges et al. teach a method of measuring hemoglobin in a blood sample (abstract). Hodges et al. measures the hemoglobin by utilizing a ferricyanide reagent and measures the resulting current of the redox reaction (col. 8, lines 62-63; col. 9, lines 44-52). Hodges et al. teach that a redox substance can be provided on the cell electrodes, walls, independent supports or be self supportive (col. 6, lines 59-62);

While Hodges et al. does not specifically teach a method of measuring hematocrit, hemoglobin and hematocrit can be measured using the device of Hodges et al. since both use the same redox substance to promote an oxidation/reduction reaction which will produce an electrochemical reaction that can be measured. This measurement can be converted to an amount of analyte present in a sample.

The court held that the configuration of a device is a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence

that the particular configuration was significant. The shifting of the position of the redox reagent with regard to the electrodes is a matter of user preference in that the redox reaction will still proceed and a current will still be measured in order to determine an analyte of interest. See *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966); MPEP 2144.04 IV B.

As taught by Hodges et al. the redox reagents may be placed on an electrode, a wall, a support or be self supportive and the device will still function in a predictable manner. Therefore, the court has held that when prior art reads on an arrangement of a part wherein the arrangement will not modify the operation of the device, the mere rearrangement of parts is unpatentable. See *In re Japikse*, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950); MPEP 2144.04 VI C. Therefore, it would have been obvious to one skilled in the art to place a redox reagent on the counter electrode and not on the working electrode in Kuhn et al. since the sensor will operate with predictable results.

<u>Regarding claims 12 and 26</u>, Kuhn et al. teach that the redox substance is ferricyanide/ferrocyanide and the application of a potential difference to the electrodes (col. 4, lines 8-10).

Hodges et al. teach that a negative voltage with respect to a voltage applied to the counter electrode is applied to the working electrode to obtain a more accurate concentration of an analyte (col. 10, lines 4-35).

Therefore, it would have been obvious to one skilled in the art to modify the power supply in Kuhn et al. to apply a voltage that is negative with respect to a voltage

applied to the counter electrode to the working electrode as taught by Hodges et al. because a more accurate concentration of analyte is obtained (col. 10, lines 4-35).

Regarding claim 15, Kuhn et al. teach a biosensor with a cover mesh 10 that delivers (i.e. acts as a channel) a blood sample 11 to a redox mesh 9 which overlays that electrodes 4 & 5 (see figure 2; col. 4, lines 1-12).

Regarding claim 27, Kuhn et al. teach a substrate 3 (col. 3, line 9). The cover mesh 10 is open toward the outside to serve as a blood supply port that leads blood to the electrode system formed on the substrate (col. 4, lines 1-14).

Regarding claim 28, see claim 27 above. Additionally, Kuhn et al. also teach a substrate that functions as a spacer 3 to create a window 7(col. 3, lines 10-15).

Regarding claim 29, Kuhn et al. teach an electrochemical sensor, but does not teach the use of a crystal homogenizing agent.

Hodges et al. teach a list of alternate substances which can also be present in the reagent portion to include any substance which provides a more stable measurement and inhibits evaporation (col. 9, lines 14-25).

Therefore, it would have been obvious to one skilled in the art to modify the additives in Kuhn et al. to include a homogenizing agent as taught by Hodges et al. to provide a more stable measurement (col. 9, lines 14-25).

Regarding claim 30, Kuhn et al. teach a measuring device for hematocrit (abstract) comprising:

- a means for applying a constant voltage (col. 3, line 19);
- a current measuring meter (i.e. detection means)(col. 3, lines19-20);
- the sensor substrate side can be held in one's hand or placed on a surface;
- a working 4 and counter electrode 5 (see figure 2).
- Additionally, Hodges et al. teach that the test strip can be combined with a meter which would function as a holding means for the sensor (col. 2, lines 1-3).
- See above claim 1 rejection concerning the redox substance located on the counter but not on the working electrode.

Regarding claim 31, Kuhn et al. teach a device that determines hematocrit utilizing a current measuring source (col. 3, lines 19-20). If a current is measured and a hematocrit level is determined, it is inherent that there be a calculation means to

perform the analysis. Additionally, a recitation of the intended use of the voltage supply must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458,459 (CCPA 1963).

2. Claims 7, 8, 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuhn et al. and Hodges et al. as evidenced by Hasegawa et al. (US 2003/0098234 A1).

Regarding claims 7, 8, 21 and 22, Kuhn et al., in view of Hodges et al., teach the use of a working and counter electrode wherein the counter electrode can be covered in a redox substance and the working electrode is not covered. Kuhn et al. teach the use of carboxymethyl cellulose (CMC) on the mesh layer which is on the working electrode (col. 3, line 29).

It is also known to directly attach the CMC layer to an electrode as evidenced by Hasegawa et al. (paragraph [0042]).

Carboxymethyl cellulose is an old and well known polymeric electrode coating and it is well known in the art that carboxymethyl cellulose is a cellulose ether and in the family of cellulose acetate which is a cellulose esters. The anionic cellulose ether, carboxymethyl cellulose (CMC), being water soluble and compatible with other bio-molecules, has excellent film forming properties. MPEP 2143.03.

Therefore, it would have been obvious to one skilled in the art to modify the working electrode of Kuhn et al. to include a carboxymethyl cellulose layer over the working electrode as evidenced by Hasegawa et al. because a carboxymethyl cellulose layer will provide transport control and has excellent film forming properties.

3. Claims 2-6 and 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuhn et al. and Hodges et al. in view of Winarta et al. (US 6,287,451 B1).

Regarding claims 2-6 and 16-20, Kuhn et al. teach either measuring the oxidation of ferrocyanide to ferricyanide or the reduction of ferricyanide to ferrocyanide (col. 5, lines 25-30).

Winarta et al. teach that potassium ferricyanide, ferrocene and its derivatives are some of the most commonly used mediators in an electrochemical sensor (col. 1, lines 49-55).

The Courts have held that the selection of a known material, which is based upon its suitability for the intended use, is within the ambit of one of ordinary skill in the art. See *In re Leshin*, 125 USPQ 416 (CCPA 1960) (see MPEP § 2144.07). The combination of familiar elements is likely to be obvious when it does no more than yield predictable results. Furthermore, the simple substitution of one known element for another is likely to be obvious when predictable results are achieved. See *KSR Int'l v. Teleflex Inc.*, 127 Sup. Ct. 1727, 1742, 82 USPQ2d 1385, 1397 (2007);MPEP § 2143.

Therefore, it would have been obvious to one skilled in the art to use the redox substance of potassium ferricyanide in Kuhn et al. as taught by Winarta et al. because

potassium ferricyanide will function with the reasonably predictable results of facilitating a redox reaction when combined with a voltage/current and the analyte in Kuhn.

4. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kuhn et al. and Hodges et al. in view of Tanike et al. (US 2004/0005721 A1).

Regarding claim 14, Kuhn et al. teach a biosensor with a working electrode and the counter electrode on the same insulating base so as to be coplanar and spaced apart from each other (see figure 2).

Kuhn et al. does not teach that the sample reaches that working electrode prior to the counter electrode.

Tanike et al. teach a biosensor that utilizes a redox mediator a spaced apart, coplanar working electrode 11 and a counter electrode 13 on a base plate 10 (figure 1; paragraph [0030]). Fluid enters the sensor through the sample pathway 23, at which time it first reaches the working electrode (upstream side) and then the counter electrode (downstream side). When reaching the working electrode oxidation results and reduction occurs at the counter electrode. Since the electrodes are interdigiated, the reduced form can be oxidized again at a neighboring working electrode. Accordingly, the value of the current flowing through the working electrode increases so that more sensitive analyte quantification is possible (paragraph [0009]).

Therefore, it would have been obvious to one skilled in the art to modify the electrodes in Kuhn et al. so that the sample reached the working electrode first and then

the counter electrode as taught by Tanike et al. because the analyte can be detected as it is oxidized and then reduced at the spaced apart electrodes (paragraph [0009]).

5. Claims 9-11 and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuhn et al. and Hodges et al. in view of Steuer et al. (US 3,922,598).

Regarding claim 9-11 and 23-25, Kuhn et al. teach an electrochemical sensor that measures hematocrit by applying a voltage and detecting a current (col. 3, lines 18-20), but does not specifically teach a voltage of 1 to 10 V which would be sufficient voltage to cause the electrolysis.

Steuer et al. teach a hematocrit sensor that applies a voltage of approximately 2 to 7 peak to peak (col. 3, line 1-2).

Therefore, it would have been obvious to one skilled in the art to use a voltage of 2 to 7 volts in Kuhn et al. as taught by Steuer et al. because at higher the voltage hematocrit percents can be more easily distinguished.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Taniike et al. (US 2001/0006149) teach a biosensor wherein a first reagent layer formed on the working electrode; and a *second reagent layer formed on the counter electrode*, wherein the first reagent layer comprises an enzyme as the main component, and the *second reagent layer comprises an electron mediator* as the main component. In this biosensor, the enzyme reaction hardly proceeds at the counter

electrode especially when the sample contains a substrate at high concentrations, since the main component of the second reagent layer on the counter electrode is the electron mediator. *Thus, the probability of collision between the enzyme and the electron mediator decreases in the sample solution in which the reagents are dissolved, so that the linearity of response current is decreased. However, since sufficient electron mediator is retained on the counter electrode for the reaction, the reaction at the counter electrode does not become a rate determining step. As a result, the linearity of response current can be maintained even up to a high substrate-concentration range* (sections 0001-0026).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dieterle whose telephone number is (571) 270-

7872. The examiner can normally be reached on Monday thru Friday, 8am to 5pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alexa Neckel can be reached on (571) 272-1446. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JMD
5/27/10

/Alexa D. Neckel/

Supervisory Patent Examiner, Art Unit 1795